UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-cv-12257-PBS Sub-Category Case No. 1:08-cv-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators,* *v.* *Baxter Healthcare Corporation.*	Judge Patti B. Saris **LEAVE TO FILE GRANTED ON 10/20/2011**

MEMORANDUM OF BAXTER HEALTHCARE CORPORATION IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

The Sun-Hamilton Complaint alleges fraudulent pricing involving two Baxter Healthcare Corporation ("Baxter") antihemophilic blood-clotting factor therapies, Recombinate and Advate.[1] Baxter has already filed a Partial Motion to Dismiss Relators' claims as they relate to Recombinate on the basis of the first-to-file doctrine.[2] The present motion offers three additional

[1] For simplicity in this memorandum, we refer to these therapies as "blood-clotting therapies." Government and other reports refer to them variously as "blood factors," "clotting factors," "antihemophilic therapies," and the like. Advate itself is an innovative recombinant blood-clotting therapy used to treat hemophilia A without the risk of infection attendant to human or animal proteins. Statement of Undisputed Material Facts ("SOF") ¶¶ 34-35; *see Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 113 (D.D.C. 2009). Advate was the first such blood-clotting therapy to be produced without any added human or animal plasma proteins. *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 113.

[2] *See* Baxter Healthcare's Partial Motion to Dismiss, Civil Action No. 1:01-cv-12257-PBS, Subcategory No. 1:08-cv-11200 (D. Mass. July 29, 2011) (Master Doc. No. 7678, Subcategory Doc. No. 125).

grounds to dismiss all claims relating to both Recombinate and Advate.[3] First, the claims are barred by the recent Settlement Agreement and Release between Baxter and Ven-A-Care, as consented to by the United States on October 3, 2011. Second, the claims are barred by the doctrine of *res judicata* as a result of this Court's dismissal with prejudice of the Ven-A-Care federal *qui tam* complaint. Third, even if the claims were not so barred, the Sun-Hamilton Relators ("Relators") still could not pursue a pricing claim relating to Advate as a matter of law, because Baxter did not begin selling Advate until August 2003, long after the Government had actively investigated and specifically acquiesced in the reimbursement of Baxter's blood-clotting therapies, including the use of average wholesale prices ("AWPs") alleged here to have been inflated.[4]

II. STATEMENT OF FACTS

The material facts necessary to decide this motion are indisputable, largely matters of public record, including this Court's own findings of facts. The Court can take judicial notice of the facts and documents cited herein. *See* Fed. R. Evid. 201; *Airframe Sys., Inc. v. Raytheon Co.*, 520 F. Supp. 2d 258, 262 (D. Mass. 2007), *aff'd*, 601 F.3d 9 (1st Cir. 2010); 21B Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure* § 5106 (2d ed. 2005).

[3] If this motion is granted, the only surviving counts (Counts IV, V, VI, XXII, and XXIII) will relate to Sun's retaliation and employment discrimination claims. *See In re Pharm. Indus. Average Wholesale Price Litig.*, Civil Action No. 01-12257-PBS, Subcategory No. 08-11200-PBS, 2010 WL 1375298, at *1 n.1 (D. Mass. Mar. 25, 2010).

[4] The arguments below – concerning the Government's knowledge of and involvement in the use of published blood-clotting therapy AWPs as a basis for reimbursement – apply to Recombinate as well as to Advate, at least for a large portion of the potential damages period. In light of the multiple grounds for dismissal, however, and the pending motion to dismiss as to Recombinate, we focus on Advate in this memorandum. Baxter reserves the right and expects to file a similar motion with respect to the Government's knowledge of Recombinate pricing, if necessary.

The pricing of Baxter's blood-clotting therapies, we show in Parts A and B below, has been the subject of litigation for more than 15 years and the subject of active, widespread federal investigation and policy analysis for even longer. In Part C below, we provide the relevant terms from the October 5, 2011 Settlement Agreement and Release, releasing all pricing claims as to Recombinate and Advate for the period June 23, 1989 through October 5, 2011.

A. The Ven-A-Care *Qui Tam*

Ven-A-Care filed its first *qui tam* complaint against Baxter and other companies in federal court in 1995.[5] The complaint, as originally filed and as amended, asserted False Claims Act ("FCA") allegations against Baxter relating to the AWPs for a variety of pharmaceutical products, including blood-clotting therapies. Ven-A-Care specifically identified Recombinate as a subject drug in its 1997 amended complaint,[6] and in its 2002 amended complaint offered detailed allegations as to the claimed wrongfulness of the AWP "spreads" for Recombinate and other therapies.[7]

[5] Complaint for Money Damages and Civil Penalties Under the False Claims Act 31 U.S.C. §§ 3729-3732, *United States ex rel. Ven-A-Care v. Abbott Labs.* (originally filed S.D. Fla. June 23, 1995), No. 1:10-cv-11186-PBS (D. Mass. June 4, 2010) (Subcategory Doc. No. 3-1).

[6] Second Amended Complaint for Money Damages and Civil Penalties Under the False Claims Act 31 U.S.C. §§ 3729-3732, *United States ex rel. Ven-A-Care v. Abbott Labs.* (originally filed S.D. Fla. Aug. 13, 1997), No. 1:10-cv-11186-PBS, at 43 (D. Mass. June 4, 2010) (Subcategory Doc. No. 5-1).

[7] Fourth Amended Complaint for Money Damages and Civil Penalties Under the False Claims Act 31 U.S.C. §§ 3729-3732, *United States ex rel. Ven-A-Care v. Abbott Labs.* (originally filed S.D. Fla. Dec. 11, 2002), No. 1:10-cv-11186-PBS, ¶¶ 177-178 & Exhibit 6 (D. Mass. June 4, 2010) (Subcategory Doc. Nos. 7-1, 7-2).

B. Government Knowledge And Approval Of The Use Of Blood-Clotting Therapy AWPs As A Basis For Reimbursement

This Court is well aware of the Government's general knowledge concerning AWP "spreads" from 1995, when Ven-A-Care filed its federal complaint, through 2001.[8] We do not reiterate that evidence here, although SOF ¶¶ 4-33 provide a non-exhaustive summary of the Government's knowledge of AWP spreads from the 1970s through the early 2000s.[9] We note simply that the reporting on AWP spreads as to particular drugs and therapies by HHS was so extensive, relentless, and thorough that this Court dubbed HHS "The Government Pit Bull" and was led to conclude that, "[b]y 2001, there was a *perfect storm of information* that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ("OIG")." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009), *cert. dismissed*, 131 S. Ct. 60 (2010) (emphasis added). Our focus here is on the Government's detailed knowledge concerning blood-clotting therapy AWPs, and on HHS's and Congress's explicit acquiescence in – indeed approval of – the use of allegedly inflated AWPs for reimbursement of those therapies.

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[8] *See, e.g.*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40-44 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009), *cert. dismissed*, 131 S. Ct. 60 (2010); *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 279-84 (D. Mass. 2006).

[9] Knowledge of AWP spreads existed at all relevant levels of government, including the President, Congress, the States, and the Department of Health and Human Services and its departments; and these government actors shared their information with one another. *See, e.g.*, SOF ¶¶ 4-7, 10, 12, 15-18, 22, 25-27. Because the Department of Health and Human Services houses the Office of Inspector General ("OIG") and the Centers for Medicare and Medicaid Services ("CMS"), and because the OIG has worked extensively with CMS pursuing instances of fraud, *see* SOF ¶¶ 1-3, Baxter considers their knowledge to be co-extensive and refers to the Department of Health and Human Services (and its predecessor, the Department of Health, Education, and Welfare), CMS (and its predecessor, the Health Care Financing Administration ("HCFA")), and the OIG together as "HHS."

1. Investigations And Concerns About The Reimbursement Of Blood-Clotting Therapies Before The Medicare Modernization Act

The Government has long recognized that blood-clotting therapies place unique demands and impose substantial costs on providers. HHS expressed concerns in the early 2000s that the reimbursement of blood-clotting therapies should be monitored to ensure it was not set too low; otherwise, providers would lose money when administering the therapies. SOF ¶¶ 23-24. As the Government Accountability Office ("GAO") later recognized, blood-clotting therapies have unique biological properties and complex dosing protocols, which contribute to special dispensing costs in the form of inventory management, storage, and shipping. SOF ¶ 28. In addition, providers incur additional costs in ancillary supplies – such as needles, syringes, and tourniquets necessary for infusing blood-clotting therapies to the hemophilia community – that are not reimbursed by Medicare. *Id.* HHS and many health professionals feared that if these costs were not reimbursed in some fashion, providers would be unwilling to continue providing the therapies at necessary levels and hemophiliacs might suffer as a result. SOF ¶¶ 23-24.

In early 2000, five years after the first Ven-A-Care complaint, in an effort to address the general problem of AWP spreads for a wide variety of drugs, the Department of Justice ("DOJ") and the National Association of Medicaid Fraud Control Units provided an alternative source of AWP data, so-called DOJ AWPs, to First DataBank, Inc., which, in turn, provided these DOJ AWPs to state Medicaid programs. SOF ¶ 22. Included among the DOJ AWPs was the AWP for Baxter's blood-clotting therapy, Recombinate, which, like the later-introduced Advate, treats a clotting Factor VIII deficiency. SOF ¶¶ 23, 34. HHS objected to the proposed revised AWPs for blood-clotting therapies, however, because the proposal conflicted with HHS's policy of ensuring adequate reimbursement for hemophilia treatments. *See* SOF ¶ 23. HHS accordingly

directed Medicare carriers[10] not to use the DOJ AWPs for blood-clotting therapies and instead to continue to reimburse on the basis of what Relators now claim are inflated AWPs:

> *[W]e have some concern about access to care related to the DOJ's wholesale prices for * * * 3 clotting factors * * * due to other Medicare payment policies associated with the provision of these drugs for the treatment of * * * hemophilia*. Therefore, you are not to consider at this time using the DOJ data for these drugs * * * to establish your Medicare allowances * * *. *For the drugs shown * * * use your usual source of average wholesale prices in your next quarterly update.*

Id. (emphasis added).

Nancy-Ann Min DeParle, then Administrator of HCFA, echoed this concern in September of 2000, when she wrote to Congress that Medicare payments for services related to the provision of blood-clotting therapies used to treat hemophilia were inadequate. SOF ¶ 24. Congressman Tom Bliley, Chair of the House Commerce Committee, responded to Ms. DeParle later that month, objecting to her policy decision but recognizing it as such:

> If this problem does indeed exist, it is one that [HHS] should have been aware of and remedied long before I first wrote to Secretary Shalala, rather than *tacitly allowing an alleged cross-subsidization between drug reimbursement rates and practice expenses to continue to exist.*

SOF ¶ 25 (emphasis added).

Nearly a year later, in September 2001, HHS produced another report on AWP spreads. SOF ¶ 26. The report noted the States' concerns about access to care for hemophilia patients and went on to say:

> Some hemophilia providers claimed that they would be unable to continue treating Medicaid recipients unless the prices for blood factors were raised. *These complaints were instrumental in two States' decisions to discontinue the use of the revised prices for blood-factor products, and have caused other States to contemplate the same action.*

[10] Medicare and Medicaid are administered by HHS through CMS. SOF ¶¶ 1-2. Medicare was previously administered by HCFA. SOF ¶ 1.

Id. (emphasis added).

2. The Medicare Modernization Act Of 2003

In January 2003, the GAO issued its own report addressing the AWP spreads for blood-clotting therapies. SOF ¶ 28. The GAO confirmed that, consistent with the information the GAO had gathered over the years, hemophilia treatment centers and homecare companies[11] were obtaining blood-clotting therapies at prices – for the therapies alone, without associated costs – significantly below the therapies' AWPs. *Id.*

The original House bill that became the Medicare Modernization Act ("MMA") was introduced on June 25, 2003. 149 Cong. Rec. H5928-01, 2003 WL 21473659 (2003). On July 15, 2003, the House Committee on Ways and Means issued a report stating: "Congress has long recognized AWP is a list price and not a measure of actual prices." Medicare Prescription Drug and Modernization Act of 2003, H.R. Rep. No. 108-178, pt. 2, at 197 (2003), *quoted in In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 283 (D. Mass. 2006). Nevertheless, Congress acquiesced in the use of AWPs – even as Congress finally began phasing out that use – when Congress passed the MMA. As this Court has concluded, "[t]he statute and the legislative history [of the MMA] indicate that by 2003, [AWP] had become a term of art. At that point, Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288.

Most significantly here, the MMA carves out an explicit exception, and sets different standards, for reimbursing the cost of blood-clotting therapies. Congress provided in the MMA

[11] Hemophilia treatment centers are federally funded facilities that provide medical care to persons with hemophilia. SOF ¶ 28. Homecare companies are also known as "specialty pharmacies." *Id.*

for a general reimbursement shift from 95% to 85% of AWP beginning in 2004, but established higher reimbursement for blood-clotting therapies, allowing reimbursement at 95% of AWP through December 31, 2004. 42 U.S.C. § 1395u(o)(1)(A)(ii), (o)(4)(A); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 44. Congress's statutory exception for blood-clotting therapies reflects similar, if not the same, access-to-care policy concerns that drove HHS's 2000 decision to use then-existing AWPs for blood-clotting therapy reimbursement rather than DOJ-calculated AWPs.

As part of the phasing out of AWPs, Congress also addressed directly the core cross-subsidization problem at the heart of reimbursement for blood-clotting therapies. The MMA authorizes Medicare providers to be reimbursed not only for the cost of the therapies themselves but also for the ancillary costs associated with treating hemophilia. The MMA provides that, for blood-clotting therapies furnished after January 1, 2005, "the Secretary shall * * * provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate." 42 U.S.C. § 1395u(o)(5)(A). The MMA directed the Secretary to consider, among other things, "[t]he mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements," and "[a]ncillary supplies and patient training necessary for the self-administration of such factors." *Id.* § 1395u(o)(5)(A)(i)-(ii).

In determining this separate payment, the Secretary was directed to review the January 2003 GAO report to Congress on clotting-factor therapy reimbursement. *Id.* § 1395u(o)(5)(A). The GAO report discusses substantial ancillary costs associated with providing blood-clotting therapies not covered by Medicare and includes the recommendation, "to reflect costs more accurately," that the Administrator establish a separate payment for the costs of delivering the

therapies to Medicare beneficiaries. SOF ¶ 28. Beginning January 1, 2005, as directed by the MMA, CMS established a separate payment, in addition to the Average Sale Price ("ASP")-based reimbursement for the blood-clotting therapies, for items and services associated with therapies in accordance with 42 U.S.C. § 1395u(o)(5)(C). *See* SOF ¶ 42.

3. Baxter Introduces Advate

The FDA approved Advate in July 2003, SOF ¶ 36, six months after the GAO report on blood-clotting therapies and one month after the first House MMA bill was introduced. Advate was introduced for sale in August 2003, SOF ¶ 37, *after* the Government had compiled detailed information about AWP spreads for blood-clotting therapies, and *after* HHS had explicitly directed carriers to use the allegedly inflated AWPs for blood-clotting therapy reimbursement. Providers and CMS classified Advate for reimbursement purposes as a blood-clotting therapy similar to other antihemophilic therapies on the market, including Recombinate, and under the same J-Code. *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 113-14, 118 (D.D.C. 2009); SOF ¶¶ 39, 41. As a result, Medicare providers received the same reimbursement for both Recombinate and Advate. *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 113-14. This was so even though Advate's selling price, as the first antihemophilic therapy produced without human or animal proteins, was higher than Recombinate's. *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 113-14.

The determination by CMS that Advate should be reimbursed under the J-Code for recombinant blood-clotting therapies – notwithstanding Advate's uniqueness and higher selling price – in fact was the subject of federal court litigation. The United States District Court for the District of Columbia upheld CMS's determination on statutory grounds, but noted in so doing that "Baxter ha[d] cause to feel treated unfairly. In 2003, it was the first to introduce a clotting

factor free of animal or human proteins, only to have its product reimbursed at less than its average sale price under the Medicare statute." *Id.* at 118.

C. The Settlement Of The Ven-A-Care Federal *Qui Tam*

On October 5, 2011, Baxter settled the federal Ven-A-Care *qui tam* and a Florida Ven-A-Care *qui tam* with the express written consent of both the United States and the State of Florida. SOF ¶ 43. Paragraph III.7 of the Settlement Agreement and Release ("Settlement Agreement and Release") provides a release to Baxter for "Covered Conduct." SOF ¶ 44. Paragraph II.E broadly defines "Covered Conduct" in terms of both the *period* of covered activities and the *subject matter* of those activities. SOF ¶ 45. The period of time covered by the release extends from June 23, 1989 through October 5, 2011, the date of the agreement's execution. *Id.* The covered subject matter includes all manner of false claims and pricing manipulation allegations covering a full range of suggested, listed, and reported prices[12] for any "Baxter Covered Drug." SOF ¶ 46. "Baxter Covered Drug" is defined to include "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party * * * including, without limitation, Baxter Covered Drugs with Labeler Codes 00338 and 00944." SOF ¶ 47. Labeler Code 00944 covers the blood-clotting therapies Recombinate and Advate. SOF ¶ 48. Thus, by its explicit

[12] Specifically, the release encompasses allegations that "one or more Baxter Parties knowingly set, reported, and/or maintained, or caused to be set, reported, and/or maintained, false, fraudulent, and/or inflated prices, including, without limitation, Average of Suggested Wholesale Price to Pharmacy, Average Wholesale Price, AWP, Suggested Wholesale Price, SWP, Price to Wholesaler and/or Distributor, Direct Price to Pharmacy, Central Purchase Price to Chain (such as Warehouse Price), Institutional or Other Contract Price (Nursing Home, Home Health Care), Other Price, Suggested List Price, List Price, Wholesale Acquisition Cost, WAC, Wholesale Net Price, Direct Price, DP, Wholesale Direct Price and/or Net Direct Price, and/or other prices reported by one or more of the Baxter Parties or published by any compendia (e.g., Redbook, First Databank)." SOF ¶ 49.

terms, the Settlement Agreement and Release releases Baxter from all FCA and pricing manipulation claims involving Recombinate and Advate through October 5, 2011.

On October 17, 2011, this Court dismissed with prejudice the Ven-A-Care claims against Baxter, "[c]onsistent with the terms of, and as limited by, the Settlement Agreement and Release." SOF ¶ 52.

III. STANDARD OF REVIEW

Summary judgment should be granted where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 139 (D. Mass. 2008) ("*Mylan*"). "'To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position.'" *Mylan*, 608 F. Supp. 2d at 139 (alteration in original) (quoting *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

IV. ARGUMENT

A. The Settlement Agreement And Release Bars All AWP And Similar Pricing Claims Against Baxter Concerning Recombinate And Advate

The Settlement Agreement and Release, by its explicit terms, releases all AWP and similar reimbursement claims involving Recombinate and Advate through October 5, 2011. SOF ¶¶ 44-49. Both Recombinate and Advate are unquestionably drugs covered by the release, among other reasons, because they both fall under Labeler Code 00944, SOF ¶ 48, which the Settlement Agreement and Release explicitly includes within "Baxter Covered Drugs." SOF ¶ 47. The Settlement Agreement and Release broadly covers every sort of pricing manipulation allegation that might be involved as to those drugs in this case. SOF ¶ 46; *see supra* note 12. It releases any claim "which has been asserted, could have been asserted, or

could be asserted in the future under any source of law * * * arising from any of the Covered Conduct." SOF ¶ 44.

One of the core policy reasons given by federal courts in finding that the FCA gives the DOJ a veto power over proposed relator settlements – a veto not exercised here – is that a relator's crafting of release language might or might not be in the Federal Government's interest. *E.g.*, *Searcy v. Philips Elecs. N. Am. Corp.*, 117 F.3d 154, 160 (5th Cir. 1997) (followed by this Court in *United States ex rel. Globe Composite Solutions, Ltd. v. Solar Constr., Inc.*, 528 F. Supp. 2d 1, 3-4 (D. Mass. 2007)). The FCA's consent requirement, 31 U.S.C. § 3730(b)(1), permits the DOJ to block *qui tam* settlements if the Government believes that the release language would preclude the United States from bringing future actions that the Government might wish to pursue. *Globe Composite Solutions*, 528 F. Supp. 2d at 3-4. The DOJ made just such an objection before this Court in connection with another AWP *qui tam* settlement – the Schering-Plough/Warrick settlement – when asserting that the scope of the proposed release was not commensurate, in the Government's view, with the consideration to be paid. United States' Memorandum in Support of Its Opposition to the Motion to Approve the Proposed Settlement Between Schering-Plough Corporation, Warrick Pharmaceuticals Corporation, California, Florida and Relator Ven-A-Care of the Florida Keys, at 10-15, Civil Action No. 1:01-cv-12257-PBS, Subcategory No. 06-11337 (Aug. 28, 2009) (Master Doc. No. 6414, Subcategory Doc. No. 392). Such objections assume that a relator's settlement with private parties has preclusive effect as to the United States, and obviously this is so. *See generally id.*[13]

[13] The very effectiveness of the FCA's private enforcement scheme depends in large measure upon a defendant's understanding that a DOJ-approved resolution of the dispute with the relator ends the dispute on the terms stated. The billions of dollars the DOJ has recovered through FCA *qui tam* actions since enactment of the 1986 amendments have come largely from settlements, the consideration for which typically is a carefully negotiated release. Ven-A-Care alone has
(footnote continued)

Here we have not only the United States' consent, but also its express conclusion that the $25 million that the United States received in connection with that settlement is "fair, adequate, and reasonable as to the United States under all the circumstances." SOF ¶ 51. The Government's agreement to the terms of a release certainly binds the Government; otherwise, that consent would be meaningless. The Settlement Agreement and Release in fact contains numerous exceptions designed to protect the United States' interest in preserving its ability to bring claims in a wide range of areas – such as, for example, claims for injury to real or personal property (*see, e.g.*, Settlement Agreement and Release ¶ III.10(c)), claims for criminal or civil or administrative tax liability (*see id.* ¶ III.10(e)), and warranty claims (*id.* ¶ III.10(f)). SOF ¶ 50. Relators, of course, have no ability to bring civil or criminal tax claims or warranty tax claims. These carve-outs serve only one purpose: to limit the settlement agreement's overall preclusive effect against the Federal Government. That preclusive effect is determined by the agreement's bargained-for release language.

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recovered more than $500 million in AWP settlements with more than $290 million collected by the Federal Government. In each of these settlements, the United States did not intervene, rather only consented. *See* Exhibit A to Stipulation of Dismissal with Prejudice of Teva Parties and Motion for Order of Dismissal with Prejudice, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:06-cv-11337-PBS, at Exhibit 2 (D. Mass. Aug. 9, 2010) (Subcategory Doc. No. 814-1); Exhibit A to Stipulation of Dismissal with Prejudice of Certain Claims Against Mylan Parties and Motion for Order of Dismissal with Prejudice, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:06-cv-11337-PBS, at Exhibit 2 (D. Mass. Dec. 29, 2010) (Subcategory Doc. No. 845-1); Exhibit A to Stipulation of Dismissal with Prejudice of Certain Claims Against Par Parties and Motion for Order of Dismissal with Prejudice, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:06-cv-11337-PBS, at Exhibit 1 (D. Mass. Aug. 26, 2011) (Subcategory Doc. No. 879-1); Consent of the United States of America to the Relator's Dismissal with Prejudice of Certain Claims Pursuant to 31 U.S.C. § 3730(b)(1), *In re Pharm. Indus. Average Wholesale Price Litig.* (Sandoz), No. 1:06-cv-11337-PBS, at Exhibit 1 (D. Mass. Sept. 9, 2011) (Subcategory Doc. No. 885-1); Exhibit 1 to Joint Notice of Settlement of Ven-A-Care Claims As to the Watson Parties and Request That Court Dismiss Settled Claims in Accordance with Stipulation of Dismissal with Prejudice of Watson Parties and Motion for Order of Dismissal with Prejudice, *In re Pharm. Indus. Average Wholesale Price Litig.* (Sandoz), No. 1:06-cv-11337-PBS, at Exhibit 5 (D. Mass. Sept. 14, 2011) (Subcategory Doc. No. 886-1).

The Sun-Hamilton Relators cannot bring FCA claims that the United States itself is barred from pursuing. An FCA relator is asserting the United States' claims; a *qui tam* relator has suffered no FCA injury himself. *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772-78 & n.4 (2000). A relator cannot have a claim separate from that of the Government. *United States ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905, 910 (9th Cir. 1998) ("A qui tam relator has Article III standing to sue only as a relator, on behalf of the government. His standing is in the nature of an assignee of the government's claim." (citation omitted)). "Regardless of whether the government opts to control or intervene in a case, the False Claims Act requires that actions 'be brought in the name of the Government.'" *Searcy*, 117 F.3d at 156 (quoting 31 U.S.C. § 3730(b)(1)). "Thus there is one claim, the government's, pursuable either by the qui tam relator on behalf of the government, or by the government on its own behalf." *Barajas*, 147 F.3d at 910. As a result, the Settlement Agreement and Release bars the Sun-Hamilton Relators from pursuing further in this action FCA claims involving the reimbursement of Recombinate and Advate.

B. The Dismissal With Prejudice Of Ven-A-Care's Federal Complaint Independently Operates To Bar Relators' Claims

"'Under the federal law of res judicata, a final judgment on the merits of an action precludes the parties or their privies from relitigating claims that were raised or could have been raised in that action.'" *Breneman v. United States ex rel. Fed. Aviation Admin.*, 381 F.3d 33, 38 (1st Cir. 2004) (citation omitted).[14] *Res judicata* applies to Relators' claims because the dismissal with prejudice of the Ven-A-Care case was a final judgment on the merits that released

[14] "The elements of a res judicata claim under federal law are: '(1) a final judgment on the merits in an earlier proceeding, (2) sufficient identicality between the causes of action asserted in the earlier and later suits, and (3) sufficient identicality between the parties in the two actions.'" *Id.* (citation omitted).

all Federal Government FCA claims concerning Recombinate and Advate, and because Relators cannot pursue here on behalf of the United States FCA claims that have been dismissed with prejudice in another action.

"A stipulated dismissal with prejudice operates as an adjudication on the merits for claim-preclusion purposes * * *." 18A Charles Alan Wright et al., *Federal Practice and Procedure* § 4435, at 135-36 (2d ed. 2002). "When a dispute of law exists between parties to a case and they agree to a settlement of that dispute and entry of a judgment with prejudice based on that settlement, then the terms of that judgment in relation to that legal issue are subject to res judicata principles." *Langton v. Hogan*, 71 F.3d 930, 935 (1st Cir. 1995). "A judgment that is entered with prejudice under the terms of a settlement, whether by stipulated dismissal, a consent judgment, or a confession of judgment, is not subject to collateral attack by a party or a person in privity, and it bars a second suit on the same claim or cause of action." *Id.* (citing 1B James Wm. Moore, *Moore's Federal Practice* ¶ .409[5] (2d ed. 1995)); *see also United States v. Cunan*, 156 F.3d 110, 114 (1st Cir. 1998).

"In the *qui tam* context, the relator is in privity with the Government." *United States ex rel. Sarafoglou v. Weill Med. Coll. of Cornell Univ.*, 451 F. Supp. 2d 613, 619 (S.D.N.Y. 2006) (citing *Barajas*, 147 F.3d at 910), and is therefore barred from FCA claims the United States cannot bring. Because "the United States is bound by the judgment in all FCA actions regardless of its participation in the case," *United States ex rel. Eisenstein v. City of New York, N.Y.*, 129 S. Ct. 2230, 2236 (2009), the United States is barred by the dismissal with prejudice in

the Ven-A-Care action from bringing FCA claims concerning Recombinate and Advate.[15] *See* SOF ¶ 52. The Sun-Hamilton Relators, consequently, are likewise barred.

C. The Government's Knowledge Of And Acquiescence In The Allegedly Wrongful Reimbursement Of Blood-Clotting Therapies Would Defeat Relators' FCA Claim As To Advate On Both "Falsity" And "Scienter" Grounds Even If The Claim Were Not Foreclosed By The Ven-A-Care Settlement Agreement And Release

Even if their claims were not otherwise barred, Relators would need to prove that Baxter knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval. *See* 31 U.S.C. § 3729(a)(1)(A). Relators therefore would need to prove both the falsity of the Advate claim and that Baxter had the requisite scienter for FCA liability. *See Mylan*, 608 F. Supp. 2d at 148. Relators could not prove falsity or the necessary scienter, or FCA damages caused by fraud,[16] with respect to Advate in light of the extensive government knowledge and acquiescence in the specifics of AWP reimbursement for blood-clotting therapies.

More than four years ago, in a decision in the Track One litigation, this Court suggested hemophilia therapies as a candidate for cross-subsidization arguments that would not work more generally as to other drugs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d

[15] It does not matter whether Ven-A-Care specifically named Advate in any of its complaints against Baxter, as Ven-A-Care did name Recombinate. *See supra* notes 6 & 7. First, the Federal Government has the right to settle a case broadly and thereby increase the *res judicata* effect of the dismissal. "The government's ability to settle cases depends on its power to give defendants releases that will protect them from more litigation based on the same invoices. If the government cannot give a defendant such a release, then the defendant might as well go to trial." *Barajas*, 147 F.3d at 910. Second, and independently, "[r]es judicata bars relitigation of all grounds of recovery that were asserted, or could have been asserted, in a previous action between the parties, where the previous action was resolved on the merits." *Id.* at 909. "It is immaterial whether the claims asserted subsequent to the judgment were actually pursued in the action that led to the judgment; rather, the relevant inquiry is whether they could have been brought." *Id.*; *see also Breneman*, 381 F.3d at 38.

[16] For reasons stated in note 19 below, Relators' claims also fail on materiality grounds.

at 37-38. This suggestion as to the uniqueness of blood-clotting therapies, we show below, was entirely correct. During all pertinent times, the Government had full knowledge of the alleged fraudulent conduct at issue, and acquiesced in – indeed, for policy reasons even directed the use of – the challenged AWPs as a basis to reimburse for blood-clotting therapies. There can be no FCA liability under these circumstances. Moreover, even if Relators could establish a misrepresentation, they could not recover FCA damages because the Government has suffered no actual damages caused by Baxter.[17]

1. The Government's Knowledge, And Indeed Approval, Of Blood-Clotting Therapy Reimbursement Based Upon Published AWPs Defeats The Falsity Element Of Relators' Claim

There can be no falsity under § 3729(a) when the Government both "possess[es] knowledge of the actual true facts of the claim," *Mylan*, 608 F. Supp. 2d at 148; *see also United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999), and acquiesces in a meaningful way in the payment of that claim, *see Mylan*, 608 F. Supp. 2d at 149. As the Seventh Circuit has observed, "[i]f the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim. In such a case, the Government's knowledge effectively negates the fraud or falsity required by the FCA." *United States ex rel. Durcholz*, 189 F.3d at 545.

[17] Baxter asserts that the Government had knowledge of, and acquiesced in, the use of AWPs for blood-clotting factors at least by June 2003, when the MMA was introduced, if not before. In any event, the latest date Relators could possibly claim that the Government did not have knowledge is December 8, 2003, when the MMA became law. *Cf. In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288 (holding that by 2003, "Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 44 (holding that the class period ended the day the MMA went into effect).

On a motion for summary judgment in *Mylan*, the defendants argued that senior government officials knew throughout the relevant time period that reported wholesale acquisition costs ("WAC") were not true prices. *Mylan*, 608 F. Supp. 2d at 150. The defendants pointed to a 2002 HHS report, which disclosed that pharmacies had paid 30.55% below WAC for generics and concluded that "'[t]he results of our review show that WAC was not a true wholesale acquisition price * * *.'" *Id.* (citation omitted). This Court stated that "the Commonwealth came to know that the WACs for generic drugs were false in certain respects beginning in 2001 or 2002," *id.*, and "[w]ith respect to the post-2002 period, a government knowledge defense is viable because the government decided to continue using WACs as a policy matter," *id.* at 152.

The government knowledge defense is not only viable here, but dispositive. Here, the Government's knowledge is long-standing, extensive, and specific as to the therapies at issue, and even involved both administrative and legislative directives countermanding the use of lower AWPs. Since at least 2000 and through 2004, the Government has recognized that blood-clotting therapies present unique concerns for reimbursement. SOF ¶¶ 23-26, 28. The Government addressed these concerns by maintaining the existing – allegedly inflated – AWPs as an appropriate basis for reimbursement. SOF ¶¶ 32-33.

As discussed above, in 2000, the Government directed Medicare carriers, for policy reasons, to use the allegedly inflated AWPs as a basis to reimburse for blood-clotting therapies. HHS instructed Medicare carriers to "use your usual source of [AWPs] in your next quarterly update." SOF ¶ 23. Baxter cannot be said to have caused a false reimbursement claim to have been submitted for Advate when HHS knew and explicitly directed the use of allegedly inflated AWPs as a basis for reimbursement for blood-clotting therapies almost three years before. *See*

United States ex rel. Durcholz, 189 F.3d at 545 (no liability where the defendant followed the Government's directions).

Whatever doubts there might have been regarding the appropriateness of this HHS directive were put to rest in 2003, the year of Advate's introduction, when Congress passed the MMA. Congress explicitly recognized in passing the MMA that "'AWP is a list price and not a measure of actual prices,'" *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 283 (quoting H.R. Rep. No. 108-178, pt. 2, at 197 (2003)),[18] and went on to carve out special reimbursement rules for blood-clotting therapies that set their reimbursement at 95% of AWP, rather than 85% of AWP or some other standard altogether, through December 31, 2004. SOF ¶ 32. Congress also established a future basis to reimburse providers separately for the unique additional costs incurred in administering the blood-clotting therapies. 42 U.S.C. § 1395u(o)(5)(A).

By 2003, when Advate was first introduced to the market under the J-Code for recombinant Factor VIII blood-clotting therapies, there had been nearly three years of government investigation and knowledge of the details underlying the reimbursement of blood-clotting therapies, followed by specific government directives on the subject of reimbursement for those therapies. As noted above, Advate was assigned the same J-Code as Recombinate (along with Baxter's competitors' therapies) and reimbursed at the same rate, notwithstanding

[18] This Court has found that "[t]he statute and the legislative history [of the MMA] indicate that by 2003, [AWP] had become a term of art. At that point, Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288; *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) ("[W]hether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it."); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) ("Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard.").

Advate's higher selling price and what the District Court for the District of Columbia saw as an unfairness to Baxter. SOF ¶¶ 39, 41; *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 118. Under these circumstances, as a matter of law, Baxter cannot be considered to have caused anyone in 2003 or thereafter to have submitted a "false" claim to the Government for Advate based upon allegedly inflated AWPs.[19]

2. The Government's Knowledge Also Negates Scienter

The FCA defines "knowing" and "knowingly" in § 3729(b) as having actual knowledge of the falsity, acting in deliberate ignorance of the truth or falsity, or acting in reckless disregard of the truth or falsity. *See* 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). Proof of the Government's knowledge also can negate the scienter element "'when the government's knowledge of * * * a [defendant's] actions is *so extensive* that the [defendant] could not as a matter of law possess the requisite state of mind to be liable under the FCA.'" *Mylan*, 608 F. Supp. 2d at 149 (brackets in original) (citation omitted); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 953 (10th Cir. 2008); *see also United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002); *United States ex rel. Werner v. Fuentez Sys. Concepts, Inc.*,

[19] The extensive government knowledge and acquiescence here also make it impossible for Relators to prove the materiality of any allegedly false claim. *See United States ex rel. Williams v. Renal Care Grp., Inc.*, No. 4:05CV985-DJS, 2008 WL 5233028, at *2 (E.D. Mo. Dec. 12, 2008) (government knowledge is relevant to materiality). Relators cannot seriously contend that, by 2003, the Government's decision to reimburse claims for blood-clotting therapies based on 95% of AWP was influenced by material falsehoods. HHS had known of AWP spreads and reimbursed such claims three years before and believed lower rates were inadequate to reimburse providers for the additional costs associated with these therapies. *Cf. United States v. Southland Mgmt. Corp.*, 95 F. Supp. 2d 629, 642-43 (S.D. Miss. 2000) (granting summary judgment because the alleged false vouchers were not material to the Department of Housing and Urban Development's ("HUD") policy-driven decision to pay), *aff'd*, 326 F.3d 669 (5th Cir. 2003); *United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 887 (8th Cir. 2003) (the EPA's knowledge and approval of operational problems showed that the allegedly withheld information may not have even been relevant to the EPA's payment decision).

319 F. Supp. 2d 682, 685 (N.D.W. Va.), *aff'd*, 115 F. App'x 127 (4th Cir. 2004); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1030-31 (D. Nev. 2006).

Relators could not plausibly argue here that Baxter *knowingly* caused a provider to submit a *false* claim for Advate where, by 2003, the Government knew AWP was a term of art not reflective of actual prices in the marketplace and where both HHS and Congress insisted upon using higher AWP reimbursement rates for blood-clotting therapies. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288. The Government's involvement in setting the reimbursement for blood-clotting therapies was so extensive that Baxter cannot, as a matter of law, have had the requisite state of mind to be found liable under the FCA. *See Mylan*, 608 F. Supp. 2d at 149 ("[T]here can be no falsity where '[t]he government knew what it wanted, and * * * got what it paid for.'" (alterations in original) (citation omitted)).

D. An Allegedly False Claim Does Not Cause Actual Damages As A Matter Of Law When The Government Pays The Claim While Knowing Of The Alleged Fraud

Even if the Court were to conclude that the Government's knowledge did not entirely vitiate Relators' FCA claim, Baxter would still be entitled to partial summary judgment on damages. The FCA distinguishes between civil penalties and actual damages. *See United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1017-19 (W.D. Mo. 1995) (court awarded civil penalties only where the Government had failed to demonstrate actual damages),[20] *aff'd*, 86 F.3d

[20] "In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(d). Thus, several federal courts have held that damages are also a necessary element of proof under the FCA. *See, e.g.*, *Young-Montenay, Inc. v. United States*, 15 F.3d 1040, 1043 (Fed. Cir. 1994); *United States v. United Techs. Corp.*, 51 F. Supp. 2d 167, 195-96 (D. Conn. 1999); *United States v. Tran*, 11 F. Supp. 2d 938, 941 (S.D. Tex. 1998); *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2d Cir. 1987).

1159 (8th Cir. 1996). The Government may only recover actual damages that the "Government sustains *because of* the act of that person." 31 U.S.C. § 3729(a)(1) (emphasis added). Accordingly, the Government cannot recover actual damages for an allegedly false claim unless it can plead and prove that specific misrepresentations made to the Government were the direct and proximate cause of the Government's losses. *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977); *United States ex rel. Fago v. M & T Mortg. Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007).

This plain reading of the statute is consistent with common-law tort causation concepts, to which this Court has previously turned in assessing FCA causation. *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003); *accord United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006). A party generally may not seek to recover damages in tort that it voluntarily elects to suffer.[21] In the FCA context, the Government's decision knowingly to pay an allegedly false claim on policy grounds creates no damages. *See United States v. Rivera*, 55 F.3d 703, 709-10 (1st Cir. 1995) (distinguishing FCA cases where the Government is "induce[d] * * * to pay out funds" from cases with only statutory penalties). If the Government pays a claim *despite knowing of its alleged falsity*, the Government cannot say that it was damaged *by reason of* that alleged falsity.

[21] The seminal opinion of *Thompson v. Libby*, 31 N.W. 52, 53 (Minn. 1886), expresses this principle well:

> [T]o allow a person who has discovered the fraud while the contract is still wholly executory to go on and execute it, and then sue for the fraud, looks very much like permitting him to speculate upon the fraud of the other party. It is virtually to allow a man to recover for self-inflicted injuries.

Thus, for example, in *United States ex rel. Butler v. Hughes Helicopter Co.*, the court held that even if the defendant were liable under the FCA, actual damages (in contrast to civil penalties) could not have been found as a matter of law where the Government was aware of the deficiencies that formed the basis of the FCA suit, yet nevertheless elected to proceed and execute its contract with the defendant. No. CV 89-5760 SVN (TX), 1993 WL 841192, at *16 (C.D. Cal. Aug. 25, 1993), *aff'd*, 71 F.3d 321 (9th Cir. 1995). "The government knew what it was getting * * *, and it got what it paid for," and thus there was no causal connection between the allegedly false statements and payment of the alleged false claim. *Id.*[22]

In sum, Relators could not recover on FCA claims even if they were not barred by the Settlement Agreement and Release. The Government not only was aware of the specifics of AWP pricing for blood-clotting therapies but also approved – both administratively and legislatively – use of those AWPs to address problems of non-reimbursement for other costs associated with the therapies' administration. This is particularly true as to Advate, the appropriateness of whose reimbursement under Medicare was litigated before a United States

[22] Government acquiescence for policy reasons can also break the chain of causation. For example, in *United States v. Southland Management Corp.*, 95 F. Supp. 2d 629 (S.D. Miss. 2000), *aff'd*, 326 F.3d 669 (5th Cir. 2003) HUD regulations conditioned payment of Section 8 housing vouchers on management's certification that its properties were in "'Decent, Safe, and Sanitary condition.'" *Id.* at 631-32. The Government brought an FCA suit against a property management company that falsely made this certification. HUD had paid the defendants' vouchers, however, even though HUD knew about the true condition of the properties and the falsity of the certifications. *Id.* at 639. Noting that a statement or claim can be material, i.e., capable of influencing action, without actually inducing reliance or causing damage, the court held that the Government had not, in fact, been damaged by the defendants' certification, in part, because "HUD's decisions to pay or not pay HAP vouchers [we]re not substantively informed by an owner's certification, but rather [we]re guided by HUD policy, as well as the practical realities of Section 8 housing programs." *Id.* at 642-43. One of these practical realities was that discontinuing payments would have worked to the detriment of tenants, *id.* at 638, just as hemophilia patients, in policymakers' views here, might have been harmed if providers had been under-reimbursed.

District Judge, who found that reimbursement to be unfair to *Baxter* although statutorily correct. *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d at 118.

V. CONCLUSION

The Court should grant Baxter's Motion for Partial Summary Judgment and dismiss with prejudice Count I of the Complaint – the FCA claims associated with Recombinate and Advate. Those claims are barred by the terms of the Settlement Agreement and Release, the doctrine of *res judicata*, and federal case authority recognizing that an FCA claim cannot survive where the level of the Government's knowledge, acquiescence, and approval is as extensive as it was here.

Dated: October 19, 2011

_/s/ Shamir Patel_____
J. Andrew Jackson
Merle DeLancey
Shamir Patel
DICKSTEIN SHAPIRO LLP
1825 Eye Street NW
Washington, DC 20006
Telephone: (202) 420-2200
Facsimile: (202) 420-2201

Peter E. Gelhaar (BBO #188310)
DONNELLY, CONROY & GELHAAR, LLP
One Beacon Street, 33rd Floor
Boston, MA 02108
Telephone: (617) 720-2880
Facsimile: (617) 720-3554

Counsel for Defendant Baxter Healthcare Corporation

CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing MEMORANDUM OF BAXTER HEALTHCARE CORPORATION IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on October 19, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

/s/ Shamir Patel

Shamir Patel
DICKSTEIN SHAPIRO LLP
1825 Eye Street NW
Washington, DC 20006
Telephone: (202) 420-2200
Facsimile: (202) 420-2201